DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

NOV 13 2013

Via UPS Delivery

Narin Ahmed Hussain, Pharm.D.
Senior Manager
Drug Regulatory Affairs
Novartis Pharmaceuticals Corporation
One Health Plaza, Building 104
Hanover, NJ 07936-1080

Re: Submission of Clinical Trial Information Pursuant to 42 U.S.C. § 282(j)
Reference Number: FDA-2013-104 (NCT00050011)

Dear Dr. Hussain:

In reviewing certain records contained in the ClinicalTrials.gov data bank, operated by the National Institutes of Health/National Library of Medicine (NIH/NLM), and records of the Food and Drug Administration (FDA), FDA has identified potential non-compliance with certain clinical trial information related to NCT00050011. Clinical trial registration and results submission requirements are described in section 801 of the Food and Drug Administration Amendments Act of 2007. Based on an initial review, your company appears to be the responsible party for NCT00050011 and it appears that the record for the referenced clinical trials may be missing clinical trial results information required to be submitted under section 402(j)(3) of the Public Health Service Act (PHS Act) (42 U.S.C. § 282(j)(3)). Your company should review this record and determine whether your company submitted all required information. If you determine that corrections, updates, or additional information should be submitted, please submit them promptly.

On October 28, 2008, and November 14, 2008, Novartis submitted Form FDA 3674, a form used to satisfy the certification requirement of section 402(j)(5)(B) of the PHS Act (42 U.S.C. § 282(j)(5)(B)), with submission of IND 55,831. In the Form FDA 3674, your company indicated that NCT 00050011 was an applicable clinical trial under section 402(j) of the PHS Act (42 U.S.C. § 282(j)). Our preliminary review of records suggests that there may be clinical trial results information, related to NCT00050011, which should have been submitted in January 2010 to ClinicalTrials.gov.

FDA intends to conduct a further review and assessment of the above-referenced clinical trial beginning 30 days after the date of receipt of this letter. If a further review and assessment of the records related to NCT00050011 results in a determination, at that time, that your company is not in compliance with all applicable requirements of section 402(j) of the PHS Act (42 U.S.C. § 282(j)), your company may receive from FDA a notice under section 402(j)(5)(C)(ii) of the PHS Act (42 U.S.C. § 282(j)(5)(C)(ii)). After FDA sends such a notice to a responsible party,

FDA could initiate an administrative action seeking a civil monetary penalty against the responsible party. Failure to submit clinical trial information required under section 402(j) of the PHS Act (42 U.S.C. § 282(j)) is a prohibited act under section 301(jj)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 331(jj)(2)). Pursuant to section 303(f)(3)(A) of the FD&C Act (21 U.S.C. § 333(f)(3)(A)), "[a]ny person who violates section 301(jj) shall be subject to a civil monetary penalty of not more than $10,000 for all violations adjudicated in a single proceeding."

Moreover, section 303(f)(3)(B) of the FD&C Act (21 U.S.C. § 333(f)(3)(B)) provides that "[i]f a violation of section 301(jj) is not corrected within the 30-day period following receipt of a [notice issued] under section 402(j)(5)(C)(ii) [of the PHS Act (42 U.S.C. § 282(j)(5)(C)(ii))], the person shall, in addition to any penalty under subparagraph (A), be subject to a civil monetary penalty of not more than $10,000 for each day of the violation after such period until the violation is corrected."

In addition to civil monetary penalties, violations of section 301(jj) of the FD&C Act (21 U.S.C. § 331(jj)) also could result in other regulatory action without further notice, such as injunction and/or criminal prosecution.

As requested, please review your company's NCT00050011 clinical trial record at http://www.clinicaltrials.gov and make any necessary submissions or corrections of clinical trial information as required under section 402(j)(3) of the PHS Act (42 U.S.C. § 282(j)(3)). If you have any questions about this letter, please call Patrick McNeilly, Ph.D., at (301) 796-2941 or email *patrick.mcneilly@fda.hhs.gov*. Please have the reference number provided above available when you call and include it with any email communications.

Sincerely,

Armando P. Zamora
Acting Director
Office of Enforcement and Import Operations
Office of Regulatory Affairs